ACCESS, FAIRNESS AND AFFORDABILITY: PROCEDURAL JUSTICE IN NICE, ANVISA AND CONITEC[1]

Ricardo Perlingeiro[2]
Christopher Newdick[3]

Everywhere, healthcare systems are making hard choices about medicines. These choices are sensitive, controversial and often result in litigation. Demand for health care exceeds the resources available and it is important for public health systems to achieve the best clinical value for money. For example, the recent report in the UK about the drug Tamiflu casts doubt on the efficacy of the treatment and its value for money to the public health system. In Brazil too, the increasing judicial review of public health decision-making illustrates the gravity of these issues and the challenges they present.

The number of lawsuits against administrative authorities in healthcare cases is growing visibly in Brazil; in 2011, there were 240,000 lawsuits. The phenomenon has taken on alarming proportions and is now being studied in a variety of arenas (political, judicial and academic). Many of the lawsuits are brought by individuals claiming medicines that are not incorporated into the public health system or not even authorized on the national market. Judicial review, when admissible, is limited to examining the litigant's arguments without considering the administrative procedures or decisions that resulted in the refusal to subsidise the drug in question, to authorise its registration or to incorporate it into the healthcare system. That stance of the Brazilian judiciary allows the claimants to obtain health benefits from the administrative authorities that are not extended to other citizens, which violates the principle of universal access to public health care and results in multiplying lawsuits.

[1] Paper at Workshop "Brazilian Pharmaceuticals Regulatory Policy Research", of the Health Law Research Center (CEPEDISA) of Health School of São Paulo University, 2014. We thank Carmen Silvia Arruda of Federal Fluminense University for her research and assistance.
[2] Professor of Public Law at Federal Fluminense University (Brazil)
[3] Professor of Health Law at University of Reading (UK)

Electronic copy available at: https://ssrn.com/abstract=2424717
Electronic copy available at: http://ssrn.com/abstract=2424717

In fact, the importance of healthcare law in Brazil has grown in proportion to this increasing uncontrollable judicial review of public health care which began in the 1980s when individuals filed claims against the administrative authorities to obtain the drugs necessary to treat AIDS. The topic has concerned healthcare specialists ever since, and more and more studies are appearing in constitutional and public administrative law journals seeking a balance between the fundamental legal values involved in the judicial review of health care.

On the one hand, health care has now come to be understood as a fundamental human right protected as an "existential minimum"; according to this line of reasoning, such claims may be asserted against the public authorities with or without the support of a pre-existing budget or specific law and should be enforceable directly by the courts with the guarantees of due process of law. On the other hand, it is becoming an increasingly widespread point of view that the principle of separation of powers is being violated in Brazil by this trend of growing judicial review of the healthcare claims, particularly with regard to the following three aspects: (a) the prerogative of the legislators and the budget to define, democratically and in advance, the State's duties of health care and the limits of such duties; (b) the need for the universality of access to public health care, to be ensured through procedures under the responsibility of administrative authorities; (c) the exclusive prerogative of the public administrative authorities to regulate and decide on questions involving highly complex technical issues such as scientific evidence and the economic viability of new drugs.

In this context, the right to health care may be understood from two different perspectives: from the point of view of substantive rights, as a fundamental right to an essential medicine or, from the point of view of procedural rights, that is to say the guarantees of access to health care, such as public health care policies, by means of the law, the budget, and administrative norms, procedures and decisions. In our understanding, the perception that the separation of powers is being violated would be reduced by shifting the focus of the debates in individual judicial claims to a consideration of the procedural parameters of the right to health care.

Electronic copy available at: https://ssrn.com/abstract=2424717
Electronic copy available at: http://ssrn.com/abstract=2424717

With that in mind, it is urgently necessary for us in Brazil to rethink the principles guiding the administrative procedures for drug registration and incorporation into the public health system. Are Anvisa (National Health Surveillance Agency) and Conitec (National Committee of Incorporation of Technologies into the Unified Health System) subject to structurally effective procedures?

The more effective the administrative procedure, the less judicial interference is required. In the case of an administrative procedure that guarantees due process of law, the tendency towards judicial intervention will be limited to assessing the reasonableness or proportionality of the authority's actions. I am referring to an administrative procedure conducted by independent and impartial authorities which are quasi-judicial, technically qualified and ensure effective, transparent and reasonably speedy access to health care. Conversely, an administrative procedure that offers no such guarantees will tend to result in much more extensive judicial review.

In Brazil, even though the Constitution requires due process of law in the administrative phase, the reality is that many procedures in effect are still tied down to the Continental European tradition in which only judges maintain effective independence, which leads to administrative procedures that are more pro forma than actually effective and encourages unlimited judicial intervention. In that situation, public administrators are always at risk of having their authority undermined because of the willingness of the courts to overrule the administrative authorities when it comes to regulating and deciding on specialised questions, including public health care. That is the consequence that we need to think about in Brazil, however, since we are adopting a judicial system with a single jurisdiction and without judges specialising in public law, a system which is showing signs of exhaustion with judicial review of public-law claims in general.

Consequently, this article mainly argues for a reinforcement of the administrative procedures in the field of health care. Our analysis will be based on the procedure by which drugs are registered and incorporated into the public health system, from a comparative perspective between

Electronic copy available at: https://ssrn.com/abstract=2424717

Brazil and the UK. The study aims to identify the efficient and inefficient aspects of the administrative procedures at NICE, Anvisa and Conitec in light of the basic principles of administrative processes guaranteeing due process.

Our analysis emphasises a variety of procedural issues essential to establishing administrative procedures which are sufficiently robust to command respect and, therefore, encourage a less intrusive judicial response. For example:

1. The basic purpose and function of the public authority: the criteria upon which public authority decisions are made should be clear. In particular, what evidence should be considered? When medicines are very expensive, are QALYs a relevant consideration and to what extent are the rights of the many balanced against individual rights? Is the authority empowered to consider single "technologies" only, or can it also advise on matters of public health generally (e.g., immunisation programmes)?

2. The legal impact of its decisions: is the authority empowered to enact laws to oblige other administrative authorities to purchase medicines, or can it only recommend? If it can only recommend, what grounds would public authorities need to have to reject the recommendation?

3. How are medicines selected for consideration, by whom and on what criteria? Can pharmaceutical companies make recommendations in their own interest, or is the *public* interest the sole valid criterion? How many medicines would normally be considered in each year and at what cost? Robust appraisal systems are expensive, so it is important to know how it will be funded.

4. What are the procedures on which appraisals will be based and on what grounds is it possible to appeal against such a decision, to whom and with what remedy? The procedures should be transparent and the decisions made should normally be published. Who will the members of the appraisal boards be and what qualifications should they possess? How will independence and impartiality be maintained, and how will commercial

Electronic copy available at: https://ssrn.com/abstract=2424717

confidentiality be preserved within the system so that transparency does not undermine information which should remain private?

5. The appraisal system should be subject to judicial review to ensure compliance with the constitutional norms, the relevance of the factors considered, the procedures followed and the rationality of the conclusions. Statutory regulations should be described in sufficient detail so as to minimize the risk of judicial review. Regulations should be clear as to the discretion available to the decision-maker so that the courts are clear as to the "range" of lawful decisions available.

Thus, we will consider: (a) The process for evaluating new technologies in NICE, Anvisa and Conitec, (b) The role of the courts in supervising these administrative procedures and (c) the residual role of judicial review of payment decisions in the NHS and SUS.

The study concludes that the proper balance between increasing demand for health care, finite public health budgets and the promotion of public interests is best achieved through public authorities structured in ways which are open and accountable. We recommend that such bodies be subject to proper procedural judicial review and that "public" access to medicines would be best served by courts which respect the public dimension of decision-making.

Electronic copy available at: https://ssrn.com/abstract=2424717